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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 4-27-92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-56, 61 are pending in the application.
   Of the above, claims 53-56 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☒ Claims 1-39, 42, 44, 46-52 are allowed.
4. ☒ Claims 40, 41, 43, 45 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The traverse of the requirement for restriction is unpersuasive, Groups II and III involve a totally different type of process. One is a cyclization reaction, the other is not. Group II involves the use of a formylating reagent (e.g. formaldehyde), while Group III would not work at all with such a reagent.

With regard to Group I and either II or III, the Examiner has complied with MPEP 806.05(f), a fact which applicant does not dispute.

Claims 40, 41, 43, 45 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Cognitive disorder is a vague umbrella term, encompassing a vast array of basically unrelated disorders which all land up affecting cognitive functioning. It has no clear boundaries. Contrary to the remarks, the examiner sees no reason why psychosis would not fit under the term "cognitive disorder". A psychotic typically cannot distinguish real from not-real, which is certainly a cognitive failure. Applicant argues that "...psychosis are not caused by cognitive disorders". Regardless of whether or not that is true, it isn't the point - The point is

that psychosis is largeably a type of cognitive disorder regardless of causation. So, contrary to the remarks, is dyslexia. Although applicant states that "dyslexia is a learning disability", it is more accurate to say that dyslexia causes an inability to learn. Dyslexia is an inability to process and comprehend certain types of visual informative, which is certainly a cognitive disorder.

Moreover, this is not enabled. It is agreed that memory is a cognitive function. But memory can be impaired by Alzheimer's Disease, concussion, virus (e.g. HIV) psychedelic drugs, multi-infarcts, alcohol (alcoholic blackouts), lobotomies, psychosis (psycholeptic amnesia), brain cancer, and even depression. There is no evidence that 5-HT_3 receptor antagonists are capable of combatting the effects of such a range of unrelated problems. The term as stated in the remarks also covers problems of "concentration" (such as ADD, Attention Deficit Disorder, a very difficult disorder to treat medically), "insight and judgement" (which is not normally considered pharmaceutically treatable) and "decreased levels of consciousness". That last one would mean applicant's compounds are useful in treating cases of coma. There is no evidence whatsoever that applicants compounds can do that any more than they can treat problems with "knowledge of general information". Arrhythmia is also not enabled. There is no definitive clinical evidence that 5-HT_3 receptor antagonists are

clinically effective for arrhythmias. The scope of "obsessive/compulsive behavior" cannot possibly be supported. For example, Bulimia and anorexia nervosa are two of the most common compulsive disorders and are considered not to be treatable pharmacologically.

In short, the utilities as set forth above are not enabled because they are entirely speculative. This places a burden on applicants to demonstrate utility commensurate with the claims (Ex parte Krepelka, 231 USPQ 746; Ex parte Jovanovics, 211 USPQ 907). For a start, Alzheimer's Disease is the most serious cognitive disorder. Applicants must present evidence that their compounds, or 5-HT_3 receptor antagonists, are in fact clinically effective.

2. "Effective for what". It says "therapeutic", but since this speculation contains such a vast array of unrelated therapies, it is unclear what claim 40 refers to. Skuballa had exactly the opposite circumstance.

The new claim is renumbered as 61. The PTOL-1449 in the PTO file has been corrected as requested.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Examiner Berch at telephone number (703) 308-4718.

Berch: ach
June 05, 1992

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